DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED RJK

August 7, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 44

Terry J. Bero
President
Unlimited Futures, Inc.
1720 Fire Lane Drive
Green Bay, Wisconsin 54301

Dear Mr. Bero:

On May 28-29, 1998 and June 3-4, 1998, the Food and Drug Administration (FDA) conducted an inspection of your drug manufacturing facility in Green Bay, WI. During that inspection our investigator observed and documented several significant violations of the Federal Food, Drug and Cosmetic Act (the Act) as described below.

* Failure to ensure that each person engaged in the manufacture, processing, packing or holding of a drug product has the education, training and experience, or any combination thereof, to enable that person to perform the assigned functions [21 CFR 211.25]. For example, the individuals involved in the manufacture and holding of over-the-counter (OTC) drug products have not received training or experience to enable them to operate in accordance with current Good Manufacturing Practices (GMPs) and written procedures as required by GMP regulations.

* Failure to have master production and control records for each drug product [21 CFR 211.186]. For example, master production and control records for each drug product produced have not been developed. OTC drug products (Sun & Fun Sunscreen, No Sweat, Antibacterial) have been manufactured.

* Failure to prepare production and control records, which include complete information relating to the production and control of each batch, for each batch of product produced [21 CFR 211.188]. For example, batch production and control records for each batch of drug product produced are incomplete.

* Failure to withhold from use each lot of components, drug product containers and closures until each lot has been sampled, tested, or examined, as appropriate for use by the quality control unit [21 CFR 211.84]. For example, there has been no system of testing and approval or rejection of components, drug product containers, and closures. There has been no specific identity test conducted on components used in the manufacture of Sun & Fun Sunscreen towel, No Sweat towel, and Antibacterial towel. Certificates of Analysis (COAs) have not been obtained for components.

* Failure to assure batch uniformity and integrity by establishing and following written procedures that describe the in-process controls, and tests or examinations to be conducted on appropriate samples of in-process materials of each batch [21 CFR 211.110]. For example, written procedures have not been established and followed that describe in-process controls, and tests or examinations to be conducted on appropriate samples of in-process materials of each batch. Proposed procedures have not been reviewed and approved by appropriate individuals.

* Failure to have a written testing program designed to assess the stability characteristics of drug products [21 CFR 211.166]. For example, a written testing program designed to assess the stability characteristics of drug products has not been developed and implemented.

* Failure to have written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written

procedures shall be followed [21 CFR 211.130]. For example, written procedures designed to assure correct labels, labeling, and packaging materials are used for drug products are not available.

* Failure to establish written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed [21 CFR 211.198]. For example, written procedures describing the handling of all written and oral complaints and the provisions for review, follow-up and documentation were not available.

We note that **PREMIER COLLECTION ANTIBACTERIAL towel, PREMIER COLLECTION SUN & FUN SUNSCREEN towel**, and **PREMIER COLLECTION NO SWEAT towel** are manufactured and marketed by your firm as over-the–counter (OTC) drug products for topical anti-microbial, sunscreen, and antiperspirant uses, respectively. These products are misbranded because the label fails to identify your firm's place of business as required by section 502(b)(1) of the Act and Title 21, Code of Federal Regulations, Part 201.1 (21 CFR 201.1). The **PREMIER COLLECTION SUN & FUN SUNSCREEN towel** is also misbranded (Section 502(e) of the Act) since the label fails to declare the amount of alcohol present as required.

In addition to the above, we note that **PREMIER COLLECTION ANTIBACTERIAL towel** contains phenol as an active antimicrobial drug ingredient. Because of its potential for causing adverse skin reactions and pending a final monograph under the OTC Drug Review, FDA recommends that products containing more than 0.5% of this ingredient bear the following warning statement: "Warning – Use according to directions. Do not apply to large areas of the body. If applied to fingers or toes, do not bandage" (21 CFR 369.20).

For your information, the safety and effectiveness of the OTC drug products cited above are being evaluated by the FDA under OTC Drug Review. Proposed regulations affecting these drugs have been published in the Federal Register as follows: 59 FR 31402, June 17, 1994, Tentative Final Monograph for Health-Care Antiseptics; 58 FR 28194, May 12, 1993, Sunscreen Drug Products for OTC Human Use, Tentative Final Monograph; and 47 FR 36492, August 20, 1982, Antiperspirant Drug Products for OTC Human Use, Tentative Final Monograph.

The proposed regulations may be used as guidelines in formulating and labeling of OTC drug products. You may check your local library or contact the Food and Drug Administration, Division of Communications Management (HFD-210), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, Maryland 20857 (1-301-827-4573) for copies of these Federal Register notices. Pending issuance of final regulations, the Agency does not object to the marketing of OTC drugs that meet both the formulation and labeling requirements described in these proposals. Such marketing, however, is subject to the risk that it may be necessary to reformulate and/or re-label these products, or seek FDA approval through the "new drug" provisions of the Act once a final rule is in effect.

The violations of the Act, described above, are not meant to be an all-inclusive list of deficiencies by your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with this statute. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the award of contracts.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within 15 working days of receiving this letter. Your response should describe the specific actions you will take, or have taken, to correct the noted violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and time within corrections will be completed. Your reply should be sent to Ms. Carrie A. Hoffman, Compliance Officer, at the address indicated on the letterhead.

If you have any questions concerning the content of this letter you may contact Ms. Hoffman by telephone at (612) 334-4100 ext. 159.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl